

constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice guidelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§ 184.1005 Acetic acid.

(a) Acetic acid ($C_2H_4O_2$, CAS Reg. No. 64-19-7) is known as ethanoic acid. It occurs naturally in plant and animal tissues. It is produced by fermentation of carbohydrates or by organic synthesis. The principal synthetic methods currently employed are oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 8, which is incorporated

by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) The ingredient is used as a curing and pickling agent as defined in § 170.3(o)(5) of this chapter; flavor enhancer as defined in § 170.3(o)(11) of this chapter; flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter; pH control agent as defined in § 170.3(o)(23) of this chapter; as a solvent and vehicle as defined in § 170.3(o)(27) of this chapter; and as a boiler water additive complying with § 173.310 of this chapter.

(d) The ingredient is used in food at levels not to exceed current good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level as served, of 0.25 percent for baked goods as defined in § 170.3(n)(1) of this chapter; 0.8 percent for cheeses as defined in § 170.3(n)(5) of this chapter and dairy product analogs as defined in § 170.3(n)(10) of this chapter; 0.5 percent for chewing gum as defined in § 170.3(n)(6) of this chapter; 9.0 percent for condiments and relishes as defined in § 170.3(n)(8) of this chapter; 0.5 percent for fats and oils as defined in § 170.3(n)(12) of this chapter; 3.0 percent for gravies and sauces as defined in § 170.3(n)(24) of this chapter; 0.6 percent for meat products as defined in § 170.3(n)(29) of this chapter; and 0.15 percent or less for all other food categories. The ingredient may also be used in boiler water additives at levels not to exceed current good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 27814, June 25, 1982]

§ 184.1007 Aconitic acid.

(a) Aconitic acid (1,2,3-propenetricarboxylic acid ($C_6H_6O_6$), CAS Reg. No. 000499-12-7) occurs in the leaves and tubers of *Aconitum napellus* L. and other *Ranunculaceae*.